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| 09/944,944      | 08/31/2001  | David Botstein       | P2548P1C18          | 2573             |

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EXAMINER

O HARA, EILEEN B

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/944,944

**Applicant(s)**

BAKER ET AL.

**Examiner**

Eileen O'Hara

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25-28,32-36 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 is/are allowed.
- 6) ☒ Claim(s) 25-28,33-36 and 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 25-28, 32-36 and 38-43 are pending in the instant application. Claims 25-28, 32-36 and 38 have been amended, claims 22-24, 231 and 37 have been canceled and claims 42 and 43 have been added as requested by Applicant in the Paper filed 15 December, 2004.

All claims are currently under examination.

#### ***Withdrawn Objections and Rejections***

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

#### ***Correction of Inventorship***

3. The inventorship has been corrected as requested in the request to correct inventorship under 37 CFR§ 1.48(b) filed December 15, 2004.

#### ***Double Patenting***

4. Applicants' statement that to the best of its present knowledge that no claims of the present application conflict with claims presented in applications containing SEQ ID NO: 362 is acknowledged.

***New Rejections***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 25-28, 33-36 and 38-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1 Claims 25-28, 33-36 and 38-43 encompass nucleic acids encoding variant polypeptides of the polypeptide of SEQ ID NO: 42, wherein the variant polypeptides inhibit neoplastic growth in tumor cells.

The Merriam Webster online medical dictionary defines neoplasm as “: a new growth of tissue serving no physiological function : TUMOR -- compare CANCER 1”. Example 30 on pages 138-139 demonstrates that the protein of SEQ ID NO: 42 can inhibit growth of established tumor cell lines. Neoplastic growth is growth of new tissue (tumor) from normal tissue, and therefore it cannot be neoplastic growth that is being inhibited, so this limitation renders the claims indefinite.

5.2 Claim 42 is also indefinite because it encompasses a nucleic acid molecule that encodes a polypeptide of SEQ ID NO: 42 with conservative amino acid substitutions. There is no upper limit on the number of substitutions which may occur, and the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 25-28, 33-36 and 38-41 remain rejected and new claims 42 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheppard et al., US Patent No. 6,197,930, issue date March 6, 2001, effective priority date August 26, 1997, for reasons of record in the previous office action, the paper mailed Sept. 9, 2003, at pages 4-5, and below.

New claims 42 and 43 encompass an isolated nucleic acid comprising a sequence that encodes a polypeptide of SEQ ID NO: 42 with conservative amino acid substitutions or 0-12 amino acid additions, deletions or substitutions, where the polypeptide inhibits neoplastic growth in tumor cells. Sheppard et al. teach that the protein of SEQ ID NO: 2 can be modified by conservative amino acid substitutions, additions or deletions (column 25, lines 24-32), and Sheppard et al. therefore anticipates the claims.

Applicants traverse the rejection and assert that a claim is anticipate only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference, and cite *Verdegaal Bros. V. Union Oil Co. of California*. Applicants have amended the claims to include the limitation that the encoded polypeptide inhibits neoplastic growth in tumor cells, and assert that as Sheppard does not teach this element, the Sheppard reference does not anticipate the current claims.

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Applicants' arguments have been fully considered but are not deemed persuasive.

Because the protein of SEQ ID NO: 42 of the instant application is identical to the protein of Sheppard, it must by necessity have the same activities as the protein of Sheppard, whether disclosed or not. The discovery of a new activity for a protein in the prior art does not make a prior art protein patentable.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 25-26 and 35, 36, and 38-41 remain rejected and new claims 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous office action, Paper No. 10, at pages 7-9, and below.

Applicants traverse the rejection on pages 14-18 of the response and assert that in an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Applicants cite *Vas-Cath Inc. v. Muhurkar*, *University of California v. Eli Lilly and, Amgen, Inc. v. Chugai Pharmaceutical Co*, as support for their position that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention based on the specification as filed. Applicants have amended the claims to include a limitation that the

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encoded polypeptides inhibit neoplastic growth in tumor cells, and therefore assert that the amended claims are not drawn to a genus of nucleic acids defined only by sequence identity, but rather to a genus defined by sequence identity correlated with function, and assert that the present situation is analogous to Example 14 on pages 53-55 of the Written Description Training Materials.

Applicants' arguments have been fully considered but are not deemed persuasive. Recitation of a biological activity in addition to the recited sequence identities would typically satisfy the written description requirements. However, as discussed above under 35 U.S.C. 112 second paragraph, the biological activity of inhibiting neoplastic growth in tumor cells is indefinite and not a true limitation, and therefore the rejection is maintained.

It is believed that all pertinent arguments have been answered.

### ***Conclusion***

8.1 Claim 32 is allowed.

8.2 Claims 25-28, 33-36 and 38-43 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final and After Final filed by RightFax should be directed to (703) 872-9306.

The customer service RightFax number is (703) 872-9305.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR  
PRIMARY EXAMINER